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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,184	09/29/2003	Edward Rhad	END-5033	1958
27777	7590	03/31/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			APANIUS, MICHAEL	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/674,184

Applicant(s)

RHAD ET AL.

Examiner

Michael Apanius

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 and 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 18-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 07122004.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species: Species I: a finger touch response apparatus drawn to figure 8-2; and Species II: a handpiece sensor mechanism drawn to figure 8-3. The species are independent or distinct because they are mutually exclusive, are not obvious variants, and have materially different designs.
  2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.
  3. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
  4. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.
- MPEP § 809.02(a).

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5. During a telephone conversation with Verne E. Kreger, Jr. on 17 March 2006 a provisional election was made without traverse to prosecute the invention of Species I, claims 1-8 and 18-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-17 and 24-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

8. Claims 2-8 are objected to because of the following informalities: at claim 2, line 3, it appears that --and-- should be inserted after "receptacles," and at claim 8, it appears that "provides" should be --provide--. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification does not enable one skilled in the art to make and use receptacles that provide a stimulus to the patient's fingers. Note that the specification does not describe how the receptacles can provide a stimulation and no element in the drawings appears to allow the receptacles to provide a stimulus to the patient's fingers. Therefore, it would require undue experimentation of one having ordinary skill in the art to make and use receptacles that provide a stimulus to the patient's fingers.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 6 and 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 6, line 1, it is unclear if "the response" refers to the "predetermined response from a patient" as set forth in claim 1 or if it refers to the "threshold response" as set forth in claim 5. At claim 18, "the

patient", "the request", "the controller", and "the response" all lack proper antecedent basis in the claims. At claim 20, "the biasing member" lacks proper antecedent basis in the claims. At claim 21, "the strain gage" and "the biasing member" lack proper antecedent basis in the claims. At claim 22, it is unclear if "the response" refers to "the response" as set forth in claim 18 or if it refers to one of the "threshold response[s]" as set forth in claims 19 and 21.

***Claim Rejections - 35 USC § 101***

13. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claims 1-8 and 18-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1, lines 8-9 state "the request assembly and/or the response assembly is attached to the patient's fingers". Claim 18, line 6 states "a finger touch response apparatus attached to the patient's fingers". These are positive recitations of the patient's fingers. Note that the human body and body parts are considered to be nonstatutory subject matter. Language such as --attachable to the patient's fingers-- instead of "attached to the patient's fingers" is recommended to overcome this rejection.

***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hickie (US 2002/0017296). Hickie discloses a conscious sedation system comprising:

a) a controller (14) which generates a request for a predetermined response from a patient, wherein the controller analyzes at least a response generated by the patient, b) a response testing apparatus (256 in figure 11 and paragraph 111) including: a request assembly (264) which communicates to the patient the request generated by the controller; and a response assembly (266) which is used by the patient to generate the response and which communicates the response to the controller, wherein the request assembly and/or the response assembly is attachable to the patient's fingers (see figure 13A and paragraphs 118-120) and wherein the response is generated by movement of the patient's fingers.

### ***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 2-8 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickie (US 2002/0017296) in view of Ellis (US 4,674,330). In regards to claim 8, Hickie teaches that the finger response apparatus can provide a stimulus to the

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patient's fingers (paragraph 120, lines 13-16). However, Hickie does not expressly disclose a finger touch response apparatus comprising electrical contacts located on receptacles, a finger touch response apparatus that generates a threshold response when electrical contacts are moved within a predetermined proximity of each other, or a strain gage. Ellis teaches a finger touch response apparatus (figure 13) for the purpose of obtaining accurate measurements regardless of the patient's precise hold on the apparatus (column 2, lines 7-14). One having ordinary skill in the art would recognize the importance of the patient's precise holding position because as a patient is undergoing sedation the placement of their grip might change on the apparatus due to diminished bodily control. Furthermore, it is well known in the art that the grip and pinch strength apparatus as taught by Ellis is an art-recognized equivalent input device to the button apparatus of Hickie. The finger touch response apparatus of Ellis comprises receptacles (2', 3') attachable onto the patient's fingers, strain gages (14', 15', 16', 17'), electrical contacts (6', 7') on the receptacles, and a biasing member (13'). Although Ellis may not expressly disclose that the exposed metal tips (6', 7') are electrical contacts, the exposed metal tips are deemed to be electrical contacts because they are capable of conducting electricity and forming electrical connections. The apparatus generates a threshold response when the electrical contacts are moved within a predetermined distance of each other and when a predetermined force is registered by the strain gage. The response is continuous and can be carried based on the patient's grip force (column 4, line 65 - column 5, line 4). It would have been obvious to one having ordinary skill in the art at the time of invention to have used the finger touch

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response apparatus as taught by Ellis in the conscious sedation system of Hickie in order to make accurate measurements regardless of the patient's precise holding position on the apparatus and because it is an art-recognized equivalent input device.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,059,830 discloses a sleep alarm device that uses electrical contacts with a biasing member. US 6,392,692 discloses a method of sleep time measurement that uses electrical contacts biased apart.

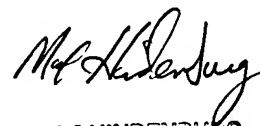
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA

  
MARK H. BENDURE  
PATENT EXAMINER  
UNIT 3736